



Receipt

PATENT  
Docket No. 398802000500

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Assistant Commissioner for Patents, Washington, D.C. 20231, on January 4, 1999.

*Jimmy Nguyen*  
Jimmy Nguyen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Richard C. ALLEN et al.

Serial No.: 09/002,413

Filing Date: January 2, 1998

For: USE OF PIGMENTED RETINAL  
EPITHELIAL CELLS FOR CREATION  
OF AN IMMUNE PRIVILEGE SITE

Examiner: Unassigned

Group Art Unit: 1644

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**REQUEST FOR A CORRECTED FILING RECEIPT**

Application Processing Division  
Customer Correction Branch  
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Washington, D.C. 20231

Dear Sir:

Please furnish the undersigned with a corrected Filing Receipt for the above-identified application. The corrections needed are as follows:

1. Add inventors --Michael L. Cornfeldt and William R. Kidwell-- as shown in the declaration previously filed;
2. Change the title to --USE OF PIGMENTED RETINAL EPITHELIAL CELLS FOR CREATION OF AN IMMUNE PRIVILEGE SITE-- as shown on page 1 of the specification as filed;

3. Change the addressee to --MORRISON & FOERSTER, 755 PAGE MILL ROAD, PALO ALTO, CA 94304--. A copy of the Revocation of Prior Power of Attorney and Power of Attorney by Inventors is enclosed; and

4. Change the Attorney Docket No. to --398802000500--.

A copy of the marked-up Filing Receipt is attached.

In the unlikely event that the transmittal letter is separated from this request and the Patent Office determines that a fee is required, applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: Jan. 4, 1999

By: Gladys H. Monroy

Gladys H. Monroy  
Registration No. 32,430

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| APPLICATION NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTORNEY DOCKET NO. | DRWGS | TOT CL | IND CL |
|--------------------|-------------|--------------|---------------|---------------------|-------|--------|--------|
| 09/002,413         | 01/02/98    | 1644         | \$2,046.00    | 8661-010-999        | 2     | 35     | 11     |

020583 MORRISON, FOERSTER 398202000500  
~~PENNIE EDMONDS~~ 753 PAGE MILL ROAD  
1155 AVENUE OF THE AMERICAS  
NEW YORK NY 10036-2711 PALO ALTO, CA 94304

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Correction Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

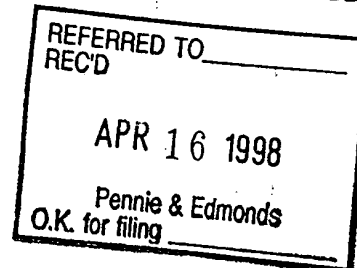
RICHARD ALLEN, FLEMINGTON, NJ, MICHAEL L. CORNFELDT, MORRISTOWN, NJ, WILLIAM R. KIDWELL, ITANVILLE, MD.

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TITLE

~~PIGMENTED RETINAL EPITHELIAL CELLS FOR CREATION OF AN IMMUNE~~  
~~PRIVILEGE SITE USE OF PIGMENTED RETINAL EPITHELIAL CELLS~~  
FOR CREATION OF AN IMMUNE PRIVILEGE SITE

PRELIMINARY CLASS: 424



COPY

DECLARATION  
AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below at 201 et seq. underneath my name.

I believe I am the original, first and sole inventor if only one name is listed at 201 below, or an original, first and joint inventor if plural names are listed at 201 et seq. below, of the subject matter which is claimed and for which a patent is sought on the invention entitled

USE OF PIGMENTED RETINAL EPITHELIAL CELLS FOR  
CREATING OF AN IMMUNE PRIVILEGED SITE

and for which a patent application:

- ☒ is attached hereto and includes amendment(s) filed on \_\_\_\_\_ (if applicable)
- ☐ was filed in the United States on \_\_\_\_\_ as Application Serial No. \_\_\_\_\_ (for declaration not accompanying application) with amendment(s) filed on \_\_\_\_\_ (if applicable)
- ☐ was filed as PCT international application Serial No. \_\_\_\_\_ on \_\_\_\_\_ and was amended under PCT Article 19 on \_\_\_\_\_ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

| EARLIEST FOREIGN APPLICATION(S), IF ANY, FILED PRIOR TO THE FILING DATE OF THE APPLICATION |         |                                      |  |
|--|---------|--------------------------------------|--|
| APPLICATION NUMBER   | COUNTRY | DATE OF FILING<br>(day, month, year) | PRIORITY CLAIMED   |
|  |         |                                      | YES <input type="checkbox"/> NO <input type="checkbox"/> |
|  |         |                                      | YES <input type="checkbox"/> NO <input type="checkbox"/> |

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below.

| APPLICATION NUMBER | FILING DATE |
|--------------------|-------------|
|                    |             |
|                    |             |

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

| APPLICATION SERIAL NO. | FILING DATE | STATUS   |         |           |
|------------------------|-------------|----------|---------|-----------|
|                        |             | PATENTED | PENDING | ABANDONED |
|                        |             |          |         |           |
|                        |             |          |         |           |

POWER OF ATTORNEY: As a named inventor, I hereby appoint S. Leslie Misrock (Reg. No. 18872), Harry C. Jones, III (Reg. No. 20280), Berj A. Terzian (Reg. No. 20060), Gerald J. Flintoft (Reg. No. 20823), David Weild, III (Reg. No. 21094), Jonathan A. Marshall (Reg. No. 24614), Barry D. Rein (Reg. No. 22411), Stanton T. Lawrence, III (Reg. No. 25736), Isaac Jarkovsky (Reg. No. 22713), Joseph V. Colaianni (Reg. No. 20019), Charles E. McKenney (Reg. No. 22795), Philip T. Shannon (Reg. No. 24278), Francis E. Morris (Reg. No. 24615), Charles E. Miller (Reg. No. 24576), Gidon D. Stern (Reg. No. 27469), John J. Lauter, Jr. (Reg. No. 27814), Brian M. Poissant (Reg. No. 28462), Brian D. Coggio (Reg. No. 27624), Rory J. Radding (Reg. No. 28749), Stephen J. Harbulak (Reg. No. 29166), Donald J. Goodell (Reg. No. 19766), James N. Palik (Reg. No. 25510), Thomas E. Friebe (Reg. No. 29258), Laura A. Coruzzi (Reg. No. 30742), Jennifer Gordon (Reg. No. 30753), Jon R. Stark (Reg. No. 30111), Allan A. Fanucci (Reg. No. 30256), Geraldine F. Baldwin (Reg. No. 31232), Victor N. Balancia (Reg. No. 31231), Albert P. Halluin (Reg. No. 25227), Samuel B. Abrams (Reg. No. 30605), Steven I. Wallach (Reg. No. 35402), Marcia H. Sundeen (Reg. No. 30893), Paul J. Zegger (Reg. No. 33821), Edmond R. Bannon (Reg. No. 32110), Bruce J. Barker (Reg. No. 33291), Adriane M. Antler (Reg. No. 32605), Ann L. Gisolfi (Reg. No. 31956), SaraLynn Mandel (Reg. No. 31853), Mark A. Farley (Reg. No. 33170), James G. Markey (Reg. No. 31636), and Charles F. Hoyng (Reg. No. 35548), all of Pennie & Edmonds LLP, whose addresses are 1155 Avenue of the Americas, New York, New York 10036, 1667 K Street N.W., Washington, DC 20006 and 2730 Sand Hill Road, Menlo Park, CA 94025, and each of them, my attorneys, to prosecute this application, and to transact all business in the Patent and Trademark Office connected therewith.

| SEND CORRESPONDENCE TO: PENNIE & EDMONDS<br>1155 AVENUE OF THE AMERICAS<br>NEW YORK, N.Y. 10036-2711 |                         |                              | DIRECT TELEPHONE CALLS TO:<br>PENNIE & EDMONDS DOCKETING<br>(212) 790-2803 |                                |
|--|-------------------------|------------------------------|--|--------------------------------|
| 2<br>0<br>1  | FULL NAME OF INVENTOR   | LAST NAME<br>ALLEN           | FIRST NAME<br>RICHARD  | MIDDLE NAME<br>C.              |
|  | RESIDENCE & CITIZENSHIP | CITY<br>FLEMINGTON           | STATE OR FOREIGN COUNTRY<br>NEW JERSEY                                     | COUNTRY OF CITIZENSHIP<br>USA  |
|  | POST OFFICE ADDRESS     | STREET<br>155 HILLCREST ROAD | CITY<br>FLEMINGTON   | STATE OR COUNTRY<br>NEW JERSEY |
| 2<br>0<br>2  | FULL NAME OF INVENTOR   | LAST NAME<br>CORNFELDT       | FIRST NAME<br>MICHAEL  | MIDDLE NAME<br>L.              |
|  | RESIDENCE & CITIZENSHIP | CITY<br>MORRISTOWN           | STATE OR FOREIGN COUNTRY<br>NEW JERSEY                                     | COUNTRY OF CITIZENSHIP<br>USA  |
|  | POST OFFICE ADDRESS     | STREET<br>22 CANTERBURY WAY  | CITY<br>MORRISTOWN   | STATE OR COUNTRY<br>NEW JERSEY |
| 2<br>0<br>3  | FULL NAME OF INVENTOR   | LAST NAME<br>KIDWELL         | FIRST NAME<br>WILLIAM  | MIDDLE NAME<br>R.              |
|  | RESIDENCE & CITIZENSHIP | CITY<br>IJAMSVILLE           | STATE OR FOREIGN COUNTRY<br>MARYLAND                                       | COUNTRY OF CITIZENSHIP<br>USA  |
|  | POST OFFICE ADDRESS     | STREET<br>10905 LOWELL COURT | CITY<br>IJAMSVILLE   | STATE OR COUNTRY<br>MARYLAND   |
| 2<br>0<br>4  | FULL NAME OF INVENTOR   | LAST NAME                    | FIRST NAME   | MIDDLE NAME                    |
|  | RESIDENCE & CITIZENSHIP | CITY                         | STATE OR FOREIGN COUNTRY   | COUNTRY OF CITIZENSHIP         |
|  | POST OFFICE ADDRESS     | STREET                       | CITY   | STATE OR COUNTRY               |
| 2<br>0<br>5  | FULL NAME OF INVENTOR   | LAST NAME                    | FIRST NAME   | MIDDLE NAME                    |
|  | RESIDENCE & CITIZENSHIP | CITY                         | STATE OR FOREIGN COUNTRY   | COUNTRY OF CITIZENSHIP         |
|  | POST OFFICE ADDRESS     | STREET                       | CITY   | STATE OR COUNTRY               |
| 2<br>0<br>6  | FULL NAME OF INVENTOR   | LAST NAME                    | FIRST NAME   | MIDDLE NAME                    |
|  | RESIDENCE & CITIZENSHIP | CITY                         | STATE OR FOREIGN COUNTRY   | COUNTRY OF CITIZENSHIP         |
|  | POST OFFICE ADDRESS     | STREET                       | CITY   | STATE OR COUNTRY               |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

|                           |                           |                           |
|---------------------------|---------------------------|---------------------------|
| SIGNATURE OF INVENTOR 201 | SIGNATURE OF INVENTOR 202 | SIGNATURE OF INVENTOR 203 |
| DATE                      | DATE                      | DATE                      |
| SIGNATURE OF INVENTOR 204 | SIGNATURE OF INVENTOR 205 | SIGNATURE OF INVENTOR 206 |
| DATE                      | DATE                      | DATE                      |

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## USE OF PIGMENTED RETINAL EPITHELIAL CELLS FOR CREATION OF AN IMMUNE PRIVILEGE SITE



### 1. INTRODUCTION

5 The present invention relates to a novel *in vivo* method for creation of a localized immunosuppressive environment in tissue. The method involves the transplanting of pigmented retinal epithelial cells into a mammal thereby producing a localized immunosuppressive environment. The transplanted  
10 pigmented retinal epithelial cells may also be used to produce therapeutic proteins or other biologically active molecules that may be useful in treatment of diseases.

### 2. BACKGROUND OF THE INVENTION

15 Certain chronic diseases result in the destruction of functional cells in affected organs. Mammals with such diseases are frequently unable to produce proteins or hormones necessary to maintain normal physiological function. In such instances, transplantation of healthy organs or cells  
20 into the affected mammal may alleviate the symptoms of the disease. The transplantation of cells and tissues is being utilized therapeutically in a wide range of disorders including but not limited to cystic fibrosis (lungs), kidney failure, degenerative heart diseases, diabetes,  
25 neurodegenerative disorders, liver failure and pancreatic failure.

Unfortunately, such transplants are often rejected by the body due to an immune response initiated in response to the foreign tissue or cells. Presently, the only recourse to  
30 prevent the rejection of the transplanted tissue is to administer immunosuppressive agents, but the individual is placed at medical risk making the immunosuppressant therapy itself more of a liability than a benefit in some cases. Therefore, the benefits of transplantation have been limited  
35 by the serious side effects of systemic immunosuppression, which is necessary if successful transplantation is to be achieved in humans.

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

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Assistant Commissioner for Patents, Washington, D.C. 20231, on December 7, 1998.

  
Jinny Nguyen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

In the application of:

Richard C. ALLEN, et al.

Serial No.: 09/002,413

Filing Date: January 2, 1998

For: USE OF PIGMENTED RETINAL  
EPITHELIAL CELLS FOR CREATION  
OF AN IMMUNE PRIVILEGE SITE

Examiner: Unassigned

Group Art Unit: 1644

REVOCATION OF PRIOR POWER OF ATTORNEY  
AND POWER OF ATTORNEY BY INVENTORS

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

I, joint inventor of the above-referenced patent application, hereby revoke all Powers of Attorney previously granted relating to this application and appoint as my attorneys or agents, with full power of substitution, association, and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected herewith:

Thomas E. Ciotti (Reg No. 21,013)  
Gladys H. Monroy (Reg No. 32,430)  
E. Thomas Wheelock (Reg No. 28,825)  
Shmuel Livnat (Reg No. 33,949)  
Antoinette F. Konski (Reg No. 34,202)  
David C. Lundmark (Reg No. P-42,815)  
Mani Adeli (Reg No. 39,585)  
Sean Brennan (Reg No. 39,917)  
Robert K. Cerpa (Reg No. 39,933)

Kate H. Murashige (Reg No. 29,959)  
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Robert Saltzberg (Reg No. 36,910)  
Catherine M. Polizzi (Reg No. 40,130)  
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Mark R. Carter (Reg No. 39,131)  
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Thomas G. Wiseman (Reg No. 35,046)  
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Nicholas Buffinger (Reg No. 39,124)  
Paula A. Borden (Reg No. 42,344)  
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all of Morrison & Foerster <sup>LLP</sup>, 755 Page Mill Road, Palo Alto, California 94304-1018,  
telephone: (650) 813-5600.

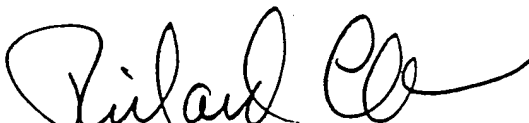
Please direct all communications relative to this application to:

Gladys H. Monroy  
Morrison & Foerster <sup>LLP</sup>  
755 Page Mill Road  
Palo Alto, California 94304-1018

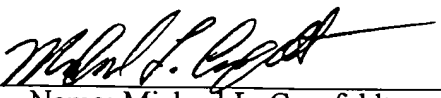
Please direct all telephone communications to Gladys H. Monroy at (650) 813-5711.

Respectfully submitted,

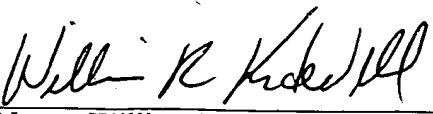
Dated: 10/30, 1998

By:   
Name: Richard C. Allen

Dated: 10/30, 1998

By:   
Name: Michael L. Cornfeldt

Dated: 11/3, 1998

By:   
Name: William R. Kidwell